Amendment to the Specification

It has been surprisingly discovered that cocoa extract, and compounds therefrom, have anti-tumor, anti-cancer or antineoplastic activity or, is an antioxidant composition or, inhibits DNA topoisomerase II enzyme activity or, is an antimicrobial or, is a cyclo-oxygenase and/or lipoxygenase modulator or, is a NO or NO-synthase modulator or, is a blood or *in vivo* glucose modulator.

Accordingly, the present invention provides a substantially pure cocoa extract and compounds therefrom. The extract or compounds preferably comprises polyphenol(s) such as polyphenol(s) enriched with cocoa procyanidin(s), such as polyphenols of at least one cocoa procyanidin selected from (-) epicatechin, (+) catechin, procyanidin B-2, procyanidin oligomers 2 through 12, preferably 2 through 4 or 4 through 12, more preferably 3 through 12, and most preferably 5 through 12, procyanidin B-5, procyanidin A-2 and procyanidin C-1.

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The present invention also provides an anti-tumor, anti-cancer or antineoplastic or antioxidant or DNA topoisomerase II inhibitor, or antimicrobial, or cyclo-oxygenase and/or lipoxygenase modulator, or an NO or NO-synthase modulator, or blood or *in vivo* glucose modulator composition comprising a substantially pure cocoa extract or compound therefrom or synthetic cocoa polyphenol(s) such as polyphenol(s) enriched with procyanidin(s) and a suitable carrier, e.g., a pharmaceutically, veterinary or food science acceptable carrier. The extract or compound therefrom preferably comprises cocoa procyanidin(s). The cocoa extract or compounds therefrom is preferably obtained by a process comprising reducing cocoa beans to powder, defatting the powder and, extracting and purifying active compound(s) from the powder.

The present invention further comprehends a method for treating a patient in need of treatment with an anti-tumor, anti-cancer, or antineoplastic agent or an antioxidant, or a DNA topoisomerase II inhibitor, or antimicrobial, or cyclo-oxygenase and/or lipoxygenase modulator, or an NO or NO-synthase modulator, or blood or *in vivo* glucose modulator comprising administering to the patient a composition comprising an effective quantity of a substantially pure cocoa extract or compound therefrom or synthetic cocoa polyphenol(s) or procyanidin(s) and a carrier, e.g., a pharmaceutically, veterinary or food science acceptable carrier. The cocoa extract or compound therefrom can be cocoa procyanidin(s); and, is preferably obtained by

reducing cocoa beans to powder, defatting the powder and, extracting and purifying active compound(s) from the powder.

Anti-cancer, anti-tumor or antineoplastic or, antioxidant, DNA topoisomerase II enzyme inhibiting, antimicrobial, cyclo-oxygenase and/or lipoxygenase modulator NO- or NO-synthase and blood or *in vivo* glucose modulating activities, or compositions containing the inventive cocoa polyphenols or procyanidins can be prepared in accordance with standard techniques well known to those skilled in the pharmaceutical or food science or veterinary art(s).

Such compositions can be administered to a subject or patient in need of such administration in dosages and by techniques well known to those skilled in the medical, nutritional or veterinary arts taking into consideration such factors as the age, sex, weight, and condition of the particular subject or patient, and the route of administration. The compositions can be co-administered or sequentially administered with other antineoplastic, anti-tumor or anti-cancer agents, antioxidants, DNA topoisomerase II enzyme inhibiting agents, or cyclo-oxygenase and/or lipoxygenase, blood or *in vivo* glucose or NO or NO-synthase modulating agents and/or with agents which reduce or alleviate ill effects of antineoplastic, anti-tumor, anti-cancer agents, antioxidants, DNA topoisomerase II enzyme inhibiting agents, cyclo-oxygenase and/or lipoxygenase, blood or *in vivo* glucose or NO or NO-synthase modulating agents; again, taking into consideration such factors as the age, sex, weight, and condition of the particular subject or patient, and, the route of administration.

Further, the invention also comprehends a kit wherein the active cocoa extract is provided. The kit can include a separate container containing a suitable carrier, diluent or excipient. The kit can also include an additional anti-cancer, anti-tumor or antineoplastic agent, antioxidant, DNA topoisomerase II enzyme inhibitor or antimicrobial, or cyclo-oxygenase and/or lipoxygenase, NO or NO-synthase or blood or *in vivo* glucose modulating agent and/or an agent which reduces or alleviates ill effects of antineoplastic, anti-tumor or anti-cancer agents, antioxidant, DNA topoisomerase II enzyme inhibitor or antimicrobial, or cyclo-oxygenase and/or lipoxygenase, NO or NO-synthase or blood or *in vivo* glucose modulating agents for co- or sequential-administration. The additional agent(s) can be provided in separate container(s) or in admixture with the active cocoa extract. Additionally, the kit can include instructions for mixing or combining ingredients and/or administration.